

Att # 4

FORM PTO-1449

INFORMATION DISCLOSURE CITATION

Atty Docket  
MHTYS 0075.02

Serial No.  
09/079,400 98,105

Applicant  
David Hugh JONES et al.

Filing Date  
May 15, 1998

Group Art Unit

**FOREIGN PATENT DOCUMENTS**

Examiner		Document Number	Date	Country	Class	Sub-Class	Translation
	AA	EP 0 475 178 A1	03/18/92	Europe			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	AB	EP 0 161 640	21/11/85	Europe			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	AC	EP 0 248 531	12/09/87	Europe			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	AD	WO 94/23738	10/27/94	PCT			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	AE	WO 95/05853	03/02/95	PCT			<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AF	MORRIS, W. et al., "Potential of polymer microencapsulation technology for vaccine innovation," <u>Vaccine</u> , Volume 12, No. 1, pages 5-11 (1994)
	AG	EPSTEIN, D.A. et al., "Alternative Delivery Systems For Peptides And Proteins As Drugs," <u>CRC Critical Review in Therapeutic Drug Carrier Systems</u> , Vol. 5, Issue 2, pages 99-139 (1988)
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Examiner

Date Considered

1/23/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
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PTO-1449

**INFORMATION DISCLOSURE STATEMENT**

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**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Sub-class	Filing Date
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**FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Sub-class	Trans-lation
AF	95/24929	09/21/95	PCT			X Yes No
AG	95/20660	08/03/95	PCT			X Yes No
AH	94/23738	10/27/94	PCT			X Yes No
AI		/ /				Yes No
AJ		/ /				Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AK	RAJASUBRAMANIAN, Ganesh et al., "Fabrication of Resorbable Microporous Intravascular Stents for Gene Therapy Applications", <u>ASAIO Journal</u> , Volume 40, No. 3, pages 584-589 (July 1994).
AL	MORRIS, William et al., "Potential of Polymer Microencapsulation Technology for Vaccine Innovation", <u>Vaccine</u> , Volume 12, No. 1, pages 5-11 (January 1994).
AM	SAH, H. K. et al., "Biodegradable Microcapsules Prepared by a W/O/W Technique: Effects of Shear Force to Make a Primary W/O Emulsion on their Morphology and Protein Release", <u>Journal of Microencapsulation</u> , Volume 12, No. 1, pages 59-69 (January 1995).
AN	NELLORE, Ranjani et al., "Application of Biodegradable Microspheres to Hepatitis B Surface Antigen Vaccination System", <u>Pharmaceutical Research</u> , Volume 8, No. 10, Page S151, Abstract No. PDD 7098 (1991).

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AK		/ /				Yes No
AL		/ /				Yes No
AM		/ /				Yes No
AN		/ /				Yes No
AO		/ /				Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AP		P. MARQUET et al., "Toxicity of tungsten", <u>The Lancet</u> , Volume 349, pages 58-59 (January 4, 1997).
AQ		D.L. MILLER et al., "Comet Assay Reveals DNA Strand Breaks Induced by Ultrasonic Cavitation In Vitro", <u>Ultrasound in Med. &amp; Biol.</u> , Volume 21, No. 6, pages 841-848 (1995).
AR		

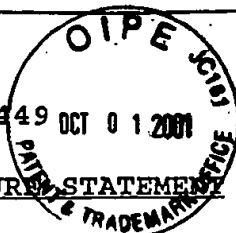
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Examiner Initial		Document Number	Date	Name	Class	Sub- class	Filing Date
DM	AA	4,897,268	06/30/90	Tice et al.			
	AB	5,075,109	12/24/91	Tice et al.			
	AC	5,407,609	04/18/95	Tice et al.			
	AD	5,580,859	12/03/96	Felgner et al.			
	AE	5,589,466	12/31/96	Felgner et al.			
	AF	5,417,986	05/23/95	Reid et al.			
	AG	5,656,469	08/12/97	Tresco et al.			
	AH	5,100,669	03/31/92	Hyon et al.			


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		Document Number	Date	Country	Class	Sub- class	Trans- lation
DA	AI	0,266,119	05/04/88	Europe			✓ Yes No
	AJ	0,302,582	02/08/89	Europe			✓ Yes No
	AK	0,333,523	09/20/89	Europe			✓ Yes No
	AL	0,706,792	04/17/96	Europe			✓ Yes No
	AM	0,471,036	02/19/92	Europe			✓ Yes No
	AN	91/110,92	10/04/90	PCT			✓ Yes No
	AO	0,737,750	10/16/96	Europe			✓ Yes No
	AP	0,451,391	10/16/91	Europe			✓ Yes No

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## FOREIGN PATENT DOCUMENTS CONTINUED



	Document Number	Date	Country	Class	Sub- class	Trans- lation
AQ	94/042,60	03/03/94	PCT			Yes ✓ No
AR	94/236,99	10/27/94	PCT			✓ Yes No
AS	94/237,38	10/27/94	PCT			✓ Yes No
AT	93/191,83	09/30/93	PCT			✓ Yes No
AU	95/212,50	08/10/95	PCT			✓ Yes No
AV	95/311,84	11/23/95	PCT			✓ Yes No
AW	95/311,87	11/23/95	PCT			✓ Yes No
AX	95/350,97	12/28/95	PCT			✓ Yes No
AY	96/002,95	01/04/96	PCT			✓ Yes No
AZ	0,127,713	12/12/84	Europe			✓ Yes No
BA	0,330,180	08/30/89	Europe			✓ Yes No
BB	0,531,497	03/17/93	Europe			✓ Yes No
BC	97/365,78	10/09/97	PCT			✓ Yes No

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
<i>DA</i>	AA1	4,293,539	10/06/1981	Ludwig <i>et al.</i>	424	19	09/12/1979
	AB1	4,623,588	10/18/1986	Nuwayser <i>et al.</i>	428	402.24	12/02/1985
	AC1	4,741,872	05/03/1988	De Luca <i>et al.</i>	264	4.7	05/16/1986
	AD1	4,818,542	04/04/1989	De Luca <i>et al.</i>	424	491	03/31/1986
	AE1	5,084,553	01/28/1992	Hess <i>et al.</i>	528	361	10/31/1990
	AF1	5,160,745	11/03/1992	De Luca <i>et al.</i>	424	487	01/09/1990
	AG1	5,820,883	10/13/1998	Tice <i>et al.</i>	424	501	06/06/1995
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<i>DA</i>	AL1	EP 0 027 662 A1	04/29/1981	Europe			Yes No
	AM1	EP 0 179 023 A2	04/23/1986	Europe			Yes No
	AN1	GB 2,185,979 A	08/05/1987	Great Britain			Yes No
	AO1	EP 0 250 038 A2	12/23/1987	Europe			Yes No
	AP1	EP 0 258 749 A2	03/09/1988	Europe			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>DA</i>	AR	1	Amagi, M. <i>et al.</i> , "Antibodies Against a Novel Epithelial Cadherin in Pemphigus Vulgaris, a Disease of Cell Adhesion," <i>Cell</i> 67:869-877 (1991).
	AS	1	Chen, S.C. <i>et al.</i> , "Protective Immunity Induced by Oral Immunization with a Rotavirus DNA Vaccine Encapsulated in Microparticles," <i>J. Virol.</i> 72:5757-5761 (July 1998).
	AT	1	Eldridge, J.H. <i>et al.</i> , "Biodegradable and Biocompatible Poly(dl-lactide-co-glycolide) Microspheres as an Adjuvant for Staphylococcal Enterotoxin B Toxoid Which Enhances the Level of Toxin-neutralizing Antibodies," <i>Infect. Imm.</i> 59:2978-2986 (1991).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	EP 0 334 062 A2	09/27/1989	Europe			Yes No
	AM2	WO 90/11092	10/04/1990	WIPO			Yes No
	AN2	EP 0 374 531 A2	06/27/1990	Europe			Yes No
	A02	WO 91/19487	12/26/1991	WIPO			Yes No
	AP2	EP 0 467 389 A2	01/22/1992	Europe			Yes No

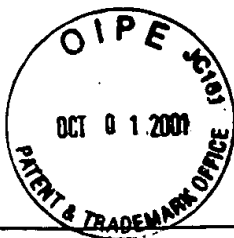
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Eldridge, J.H. <i>et al.</i> , "Controlled Vaccine Release in the Gut-Associated Lymphoid Tissues. 1. Orally Administered Biodegradable Microspheres Target the Peyer's Patches," <i>J. Controlled Release</i> 11:205-214 (1990).
	AS	2	Florence, A.T. "The Oral Absorption of Micro- and Nanoparticulates: Neither Exceptional Nor Unusual," <i>Pharm. Res.</i> 14:259-266 (March 1997).
	AT	2	Gref, R. <i>et al.</i> , "Biodegradable Long-Circulating Polymeric Nanospheres," <i>Science</i> 263:1600-1603 (1994).

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DR	AL3	WO 92/06666	04/30/1992	WIPO			Yes No
	AN3	WO 94/04171	03/03/1994	WIPO			Yes No
	AN3	WO 94/09898	05/11/1994	WIPO			Yes No
	AO3	CA 2,126,685	05/11/1994	Canada			Yes No
	AP3	WO 94/28873	12/22/1994	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

DR	AR	3	Heard, "HLA and autoimmune disease," in <i>HLA and Disease</i> , Academic Press, San Diego, CA, chapter 7 (1994).
	AS	3	Hedly, M. L. "Genetic Modulation and Antigen Presentation," in <i>MHC Molecule: Expression, Assembly, and Function</i> , chapter 17 (1996).
	AT	3	Jacobs S.C. <i>et al.</i> , "Protection elicited by a replication-defective adenovirus vector expressing the tick-borne encephalitis virus non-structural glycoprotein NS1," <i>J. Gen. Virol.</i> 75:2399-2402 (1994).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
DR	AL4	EP 0 635 261 A1	01/25/1995	Europe			Yes No
	AM4	WO 95/07072	03/16/1995	WIPO			Yes No
	AN4	WO 95/17167	06/29/1995	WIPO			Yes No
	AO4	WO 96/11671	04/25/1996	WIPO			Yes No
	AP4	WO 96/29998	10/30/1996	WIPO			Yes No

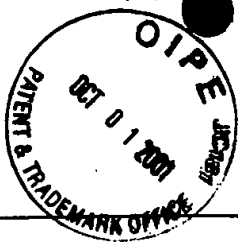
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

DR	AR	4	Jacobs, S.C. et al., "High-Level Expression of the Tick-Borne Encephalitis Virus NS1 Protein by Using an Adenovirus-Based Vector: Protection Elicited in a Murine Model," <i>J. Virol.</i> 66:2086-2095 (1992).
	AS	4	Jepson, M. et al., "Comparison of Poly(DL-Lactide-co-Glycolide) and Polystyrene Microsphere Targeting to Intestinal M Cells," <i>J. Drug Targeting</i> 1:245-249 (1993).
	AT	4	Jeyanthi, R. et al., "Development of a Biodegradable Microsphere Formulation for the Sustained Release of a Bioactive Peptide," <i>Pharm. Res.</i> 8:151(S), pdd 7079 (1991).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Jones, D.H. <i>et al.</i> , "Orally Administered Microencapsulated <i>Bordetella pertussis</i> Fimbriae Protect Mice from <i>B. pertussis</i> Respiratory Infection," <i>Infect. Immun.</i> 64:489-494 (February 1996).
	AS	5	Jones <i>et al.</i> , "Poly(DL-lactide-co-glycolide)- encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration," <i>Vaccine</i> 15:814-817 (June 1997).
	AT	5	Jones, <i>et al.</i> , "Oral delivery of Poly(lactide-co-glycolide) encapsulated vaccines," <i>Behring Inst. Mitt.</i> 98:220-228 (February 1997).

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<i>On</i>	AR	<u>6</u>	Jones, D.H. <i>et al.</i> , "Immune Responses Following Oral and Parental Administration of Plasmid DNA Encapsulated in Poly(lactide-coglycolide) Microparticles," <i>Int. Meeting on Nucleic Acid Vaccines</i> , Bethesda, MD, Abstract and attached Figures 2 and 3 and Figure entitled "Stool IgA Response to PLG-Encapsulated DNA (February 5-7, 1996).
<i>J</i>	AS	<u>6</u>	Jones, D.H. <i>et al.</i> , "Oral Delivery of Micro-Encapsulated DNA Vaccines, " <i>Dev. Biol. Stand.</i> 92:149-155 (1998).
<i>J</i>	AT	<u>6</u>	Jones, D.H. <i>et al.</i> , "Protection of mice from <i>Bordetella pertussis</i> respiratory infection using microencapsulated pertussis fimbriae," <i>Vaccine</i> 13:675-681 (May 1995).

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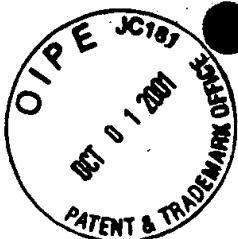
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Dr	AR	Z	Jones, D.H. <i>et al.</i> , "PLG microencapsulation of vaccine antigens," <i>J. Biotech.</i> 44:29-36 (1994).
J	AS	Z	Kreuter, J. "Nanoparticles and microparticles for drug and vaccine delivery," <i>J. Anat.</i> 189:503-505 (December 1996).
J	AT	Z	Lewis, K. <i>et al.</i> , "Biodegradable poly(L-lactic acid) matrices for the sustained delivery of antisense oligonucleotides," <i>J. Controlled Release</i> 37:173-183 (November 1995).

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Dr	AR	8	Murphy, D. <i>et al.</i> , "A novel MHC class II epitope expressed in thymic medulla but not cortex," <i>Nature</i> 338:765-768 (1989).
J	AS	8	Neutra, M. <i>et al.</i> , "Epithelial M Cells: Gateways for Mucosal Infection and Immunization," <i>Cell</i> 86:345-348 (August 1996).
V	AT	8	O'Hagan, D.T. "The intestinal uptake of particles and the implications for drug and antigen delivery," <i>J. Anat.</i> 189:477-482 (December 1996).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

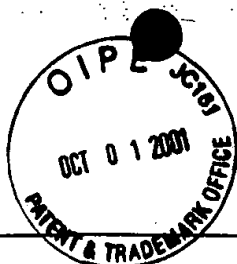
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Puyal, C. <i>et al.</i> , "A new cationic liposome encapsulating genetic material. A potential delivery system for polynucleotides," <i>Eur J Biochem.</i> 228:697-703 (March 1995).
	AS	2	Shimoda, S. <i>et al.</i> , "HLA-DRB4 0101-restricted Immunodominant T Cell Autoepitope of Pyruvate Dehydrogenase Complex in Primary Biliary Cirrhosis: Evidence of Molecular Mimicry in Human Autoimmune Diseases," <i>J. Exp. Med.</i> 181:1835-1845 (May 1995).
	AT	2	Steinman, L. "Escape from 'Horror Autotoxicus': Pathogenesis and Treatment of Autoimmune Disease," <i>Cell</i> 80:7-10 (January 1995).

EXAMINER

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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1581.0270001/RWEAPPLICATION NO.  
09/079,400 898,105APPLICANT  
JONES et al.FILING DATE  
May 15, 1998GROUP  
1643

## U.S. PATENT DOCUMENTS

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

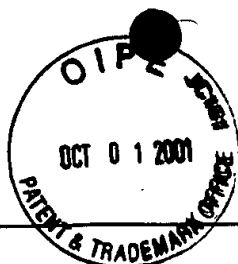
	AR	10	Tomlinson, E. and Rolland, A.P. et al., "Controllable gene therapy Pharmaceuticals of non-viral gene delivery systems," <i>J. Controlled Release</i> 39:357-372 (March 1996).
	AS	10	Visscher, G.E. "Biodegradation of and tissue reaction to 50:50 Poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mater. Res.</i> 19:349-365 (1985).
	AT	10	Dialog File 351, Accession No. 81-329240/198119, Derwent WPI English language abstract for Document AL1 (EP 0 027 662 A1).

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11/23/03

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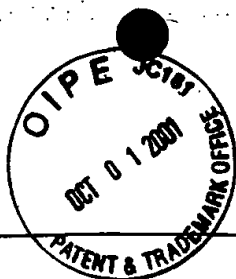
	AR	11	Dialog File 351, Accession No. 86-108252/198617, Derwent WPI English language abstract for Document AM1 (EP 0 179 023 A2), 86.
	AS	11	Dialog File 351, Accession No. 92-166845/199220, Derwent WPI English language abstract for Document AL3 (WO 92/06666), 92.
	AT	11	Dialog File 351, Accession No. 94-167187/199420, Derwent WPI English language abstract for Document AN3 (WO 94/09898), 1994.

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Pa	AR	12	Dialog File 351, Accession No.95-123218/199516, Derwent WPI English language abstract for Document AM4 (WO 95/07072), 1995,
L	AS	12	Dialog File 351, Accession No.95-240449/199531, Derwent WPI English language abstract for Document AN4 (WO 95/17167), 1995.
	AT		

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